

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA,

Plaintiff,

v.

Case No. 10-cv-158

FILED UNDER SEAL

Undetermined quantities of the articles of drugs listed below, in various sizes and types of containers, labeled and unlabeled, which are in the possession of Beehive Botanicals, Inc., 16297 West Nursery Road, Hayward, Wisconsin:

Finished Products:

Propolis Extract - Alcohol Free
Propolis Tincture 50%
Propolis Tincture 65%
Propolis Capsules, 500 mg
Propolis Tablets, 500 mg
PropolPom Capsules, 500 mg
Propol Dent Gum
Propolis Derma Cream
Propolis & Herb Throat Spray
Propol-Guard Lip Balm
Whole Grain Pollen Capsules, 500 mg
Pollen Tablets, 500 mg
Pollen Granules
Royal Jelly Capsules, 500 and 1000 mg, pure
Royal Jelly in Honey, 15,000 and 30,000 mg
Fresh Royal Jelly
Bee Therapy Foot Balm
Bee Therapy Hand Salve
Honey and Pollen Body Moisturizer
Hydrating Cream
Moisturizing Facial Cleanser
Conditioning Shampoo
Moisturizing Conditioner
Honey and Cornmeal Bath Bar
Honey Silk Night Cream

Bulk Components:

Propolis Extract (Propolis Bee Concentrate)
Propolis, unprocessed or washed
Royal Jelly Powder

Fresh Royal Jelly)
Bee Pollen (Granules))
Honey,)
and)
all articles of drugs comprised, in part,)
of these components,)
Defendants.)

VERIFIED COMPLAINT FOR FORFEITURE *IN REM*

The United States of America ("United States"), by its attorney Stephen P. Sinnott, United States Attorney for the Western District of Wisconsin, by Leslie K. Herje, Assistant United States Attorney for that District, hereby states and alleges as follows:

NATURE OF THE ACTION

1. This Complaint is filed by the United States, and requests seizure and condemnation of articles of drugs, as described in the caption, in accordance with the Federal Food, Drug, and Cosmetic Act ("Act"), 21 U.S.C. § 301 *et seq.*

2. There are at Hayward, Wisconsin, in the possession of Beehive Botanicals, Inc. ("Beehive Botanicals"), 16297 West Nursery Road, or elsewhere within the jurisdiction of this Court, articles of drugs, as described in the caption, which articles consist in whole or in part of components that were shipped in interstate commerce from outside the state of Wisconsin (the "Articles").

JURISDICTION AND VENUE

3. Plaintiff brings this action *in rem* in its own right to condemn and forfeit the Articles. This Court has jurisdiction over an action commenced by the United States

under 28 U.S.C. § 1345 and 21 U.S.C. § 334, which provides this Court with jurisdiction over seizures brought under the Act.

4. This Court has *in rem* jurisdiction over the articles because they are located in the Western District of Wisconsin. Upon the filing of this Complaint, the United States requests that this Court issue an arrest warrant *in rem* pursuant to Federal Rules of Civil Procedure Supplemental Rule G(3)(b), which the United States will execute upon the Articles pursuant to Supplemental Rule G(3).

BASIS FOR FORFEITURE

5. The Articles are drugs within the meaning of 21 U.S.C. § 321(g)(1), in that they may not be introduced or delivered for introduction into interstate commerce pursuant to 21 U.S.C. § 355(a), because they are “new drugs” within the meaning of 21 U.S.C. § 321(p) and no approvals of applications filed pursuant to 21 U.S.C. § 355(b) or exemptions from such requirements pursuant to 21 U.S.C. § 355(i) are in effect for such drugs.

6. The Articles are misbranded while held for sale after shipment of one or more of their components in interstate commerce, within the meaning of the Act, 21 U.S.C. § 352(f)(1), in that their labeling fails to bear adequate directions for use and they are not exempt from such requirement under 21 C.F.R. § 201.115 since the Articles are unapproved new drugs.

7. By reason of the foregoing, the Articles are held illegally within the jurisdiction of this Court and are liable to seizure and condemnation pursuant to 21 U.S.C. § 334.

FACTS

8. In a Warning Letter issued on March 2, 2007, the Food and Drug Administration ("FDA") advised Beehive Botanicals that use of disease claims on promotional literature and its website cause the products to be drugs under 21 U.S.C. § 321(g) and new drugs under 21 U.S.C. § 355 and 21 U.S.C. § 321(p). Counsel for Beehive Botanicals responded by letter dated March 21, 2007, stating that Beehive Botanicals was undertaking full correction of the violations, but requesting a time extension, which was granted by the FDA. Beehive Botanicals subsequently submitted proposed new labeling, which the FDA found acceptable under the Act.

9. During a subsequent FDA inspection, conducted from September 23 to October 1, 2009, an FDA investigator found that Beehive Botanicals continued to include, on its own website, links to another website containing representations and claims that materials derived from bees were useful in treating various diseases. Specifically, the website Beehive Botanicals uses to sell its products, www.beehivebotanicals.com, links to www.apitherapy.org, a website containing drug claims for ingredients derived from bees (propolis, royal jelly, bee pollen, and honey). Those ingredients are used in the production of the Articles sold by Beehive Botanicals. The www.apitherapy.org site also links back to www.beehivebotanicals.com.

10. During the September/October 2009 inspection, the FDA investigator discussed with Beehive Botanicals' management the violations he observed with the promotional claims made on websites linked to www.beehivebotanicals.com. Links to several websites accessible through the Beehive Botanicals' website, including www.apitherapy.org, include drug claims for one or more of the ingredients listed in the caption of this Complaint.

11. Another website maintained by Beehive Botanicals and bearing its logo, www.bee-propolis.org/bee-products-info.html, also contains claims that the Articles are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans. This website links to Beehive Botanicals' home webpage, which Beehive Botanicals uses to sell its products.

12. Beehive Botanicals ships labeling with certain of its products in which it claims that the ingredients in Beehive Botanicals' products can be used in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans.

13. Examples of the drug claims for bee-derived components in the Articles' labeling, include, but are not limited to, the following:

(a) "Propolis, also known as "Russian penicillin" . . . is capable of acting as an anti-inflammatory. It can help with symptoms of arthritis, boils . . . asthma, dermatitis, ulcers, and inflammatory bowel diseases. Propolis has also been found to have antimutagenic effects, which may aid in the prevention of cancer";

(b) "Propolis is proven to have distinct antibacterial, antiviral and antifungal properties . . .";

(c) "[B]ee propolis . . . with its antibiotic properties, has astonished doctors";

(d) "Propolis has proved effective in helping to deal with a wide variety of infections and illnesses, including ulcers, colds, . . . hypertension, pharyngitis, and periodontal problems . . .";

(e) "[P]ropolis has antiproteolytic, bactericidal, and bacteriostatic action . . .";

(f) "[P]ropolis . . . when it is administered along with penicillin or other antibiotics, [] increases the latter's effectiveness as much as 10 to 100 fold";

(g) “[P]ropolis fortifies the activity of various antibiotics . . . [as it] strengthens the bacteriostatic activity of tetracycline, neomycin and plymycin . . . And enhances the activity of streptomycin, penicillin, neomycin, plymycin, and tetracycline . . .”;

(h) “Common indications for oral ingestion of honey include: insomnia, anorexia, stomach and intestinal ulcers, constipation, osteoporosis . . . [it also] act[s] as a broad-spectrum antibiotic . . . [and has] antifungal and antiviral properties”;

(i) “Indications for the external application of honey include treatment of athlete’s foot, eczema, lip sores, and both sterile and infected wounds resulting from accidents, surgery, bed sores, or burns”;

(j) “[P]ollen has a variety of anti-inflammatory, anti-cancer, and anti-arthritis properties. Its anti-inflammatory and anti-allergic properties . . . Pollen has been reported to be useful in many other medical conditions including: varicose veins, high cholesterol . . . infertility, impotence, anorexia, obesity, constipation, diarrhea, hypertension, prostatitis, depression . . . and recovery from illness and surgery . . .”;

(k) “Royal jelly . . . is . . . used . . . to prevent and ameliorate a wide variety of medical conditions. These include, but are not limited to: anxiety, arteriosclerosis, arthritis, bone fractures, asthma, depression . . . impotence, insomnia, liver and kidney disease, stomach ulcers . . . varicose veins . . . high and low blood pressure . . .”;

(l) “Royal Jelly is known to aid in liver disease, pancreatitis, insomnia, stomach ulcers, kidney disease, bone fractures and skin disorders . . . successfully combats whooping cough . . . Benefits can also be obtained in cases of bronchitis, migraine, stomach and gallbladder troubles, digestive disorders . . . These and many other health [] problems can be improved considerably, if not cured . . . royal jelly

contains an antibiotic almost one-quarter as active as penicillin, without the side effects . . . "; and

(m) "Royal Jelly has antibiotic and bactericidal action against human tuberculosis . . . given time, Royal Jelly will help to do what other treatments have failed to accomplish . . .".

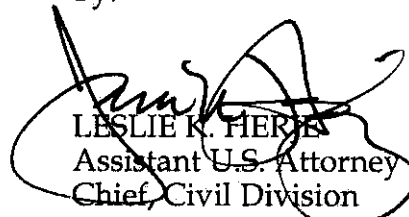
WHEREFORE, the United States requests that a warrant of arrest for the Articles of drugs, as identified in the caption, be issued; that due notice be given to all parties to appear and show cause why the seizure and condemnation should not be decreed; that the judgment be entered declaring the Articles of drugs be condemned and disposed of according to law; and that the United States be granted such other and further relief as this Court may deem just and proper, together with costs and disbursement of this action.

Dated this 25th day of March, 2010.

Respectfully submitted,

STEPHEN P. SINNOTT
United States Attorney

By:

A handwritten signature in black ink, appearing to read "Leslie K. Herzig", is written over a circular stamp. The signature is fluid and cursive.

LESLIE K. HERZIG
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OF COUNSEL:

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Office of General Counsel

DECLARATION

I am a Compliance Officer for the Food and Drug Administration, United States Department of Health and Human Services, and am familiar with the investigation of this case and the evidence gathered in support. I have personally reviewed the Internet websites in question, the labeling obtained by FDA, and FDA's official records related to this case.

I have read the contents of the foregoing Complaint for Forfeiture and based on my personal knowledge of the evidence obtained in the course of my official duties of and as a result of my review of FDA's official business records, the statements contained therein are true to the best of my knowledge and belief.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 24th day of March, 2010.



Tyra Wisecup, Compliance Officer
Food and Drug Administration
United States Department of Health and
Human Services